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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Dov Malonck

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07/09/2007

WOLF, BLOCK, SHORR AND SOLIS-COHEN LLP

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

07/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/849,637

Applicant(s)

MALONEK ET AL.

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-33, 36-41, 43-48, 50-61, 63-78, 80, 82, 84 and 86-94 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 41, 43-45, 74-78, 80, 82, 84, 86-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/2/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5-18, 20-33, 36-40, 45/(5-18, 20-33, 36-40), 46-48, 50-61, and 63-73 .

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 2/2/07 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein for that reference has not been considered.

Response to Amendment

The declaration under 37 CFR 1.132 filed 1/31/07 is insufficient to overcome the rejection of the claims based upon the 112 first paragraph rejection as set forth in the last Office action because: According to MPEP 716.09, “[A]ffidavits or declarations presented to show that the disclosure of an application is sufficient to one skilled in the art are not acceptable to establish facts which the specification itself should recite. In re Buchner, 929 F.2d 660, 18 USPQ2d 1331 (Fed. Cir. 1991) (Expert described how he would construct elements necessary to the claimed invention whose construction was not described in the application or the prior art; this was not sufficient to demonstrate that such construction was well-known to those of ordinary skill in the art.); In re Smyth, 189 F.2d 982, 90 USPQ 106 (CCPA 1951).

The specification does not describe any facts on how to make or enable one skilled in the art to make an electrode with a capacitance of 300-3000 microfarads except to list several materials used for the electrode, such as platinum iridium (page 8), briefly states that porous materials increase the capacitance and minimize impedance (page 22), and discloses that a capacitance of 300-3000 microfarads is used (page 20). As seen in the 112 first paragraph

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rejection set forth in this action or the previous action, several questions arise as to how to make an electrode with a capacitance of 300-3000 microfarads. In addition, the declaration shows in paragraphs 40-52 that numerous technical steps are needed to make an electrode which has a capacitance of 300-3000 microfarads.

Election/Restrictions

Claims 46-48 and 50-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/26/03.

Claims 5-18, 20-33, 36-40, 45/(5-18, 20-33, 36-40), and 63-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made by election by original presentation in the office action dated 12/10/04 and **without** traverse in the reply filed on 6/10/05.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 41-44, 45/(19 and 41-44) and 74-94 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The subject matter not disclosed is how to make a unitary/signal delivery electrode having a capacitance greater than 300 microfarads and less than 3000 microfarads, in combination with the other elements in the claim. The specification lists several materials used for the electrode (page 8), such as platinum iridium, briefly states that porous materials increase the capacitance and minimize impedance (page 22), and discloses that a capacitance of 300-3000 microfarads is used (page 20). But, the specification is silent as to how the delivery electrode is made to have a 300-3000 microfarad capacitance. Several questions arise as to how to make the electrode have a capacitance of 300-3000 microfarads, such as: How is the porousness changed? Is it increased or decreased for the unitary/signal electrode? How is the porousness changed for each of the different electrode materials? How does it affect the capacitance? How does the length, electrode material, thickness of electrode material, etc. affect the capacitance (and in combination with the porousness)?

In addition, one skilled in the art could not practice/make the invention without undue experimentation to arrive at an electrode with a capacitance of 300-3000 microfarads. Several factors have been considered to arrive at this conclusion, such as:

The amount of direction provided by the applicant is minimal. Several common/conventional electrode materials are listed in the specification (page 8), but only a brief mention is made that porous materials increase the capacitance (page 22).

As stated above, several questions arise as to how to make the electrode and therefore undue experimentation would be necessary.

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The applicant has provided no working examples in the specification.

The state of the prior art is silent as to how to make an electrode with a capacitance of 300-3000 microfarads (and using porousness and/or the specific electrode materials). The examiner has provided a recent patent (Ekwall) showing the use of electrode thickness, not porousness, to change the capacitance, but the capacitance is only changed to 1-15 microfarads. In addition, Mund and Botvidsson are two examples that show the numerous steps and considerations necessary to provide a high capacitance and/or do not show the use of the steps to make other high capacitance electrodes using materials listed in the applicants specification and claims, such as titanium coated with iridium oxide, platinum iridium coated with titanium nitride, platinum iridium coated with sintered platinum, or pyrolitic carbon. In addition, the applicant argues on page 16 of the reply dated 6/10/05 that the same materials used by applicant (titanium nitride, iridium oxide) at most have a capacitance of 150 microfarads, and therefore more guidance on how to make the electrode is needed.

Finally, the claims are very broad (a common electrode and connector) and only really have a limitation directed to the electrode having a 300-3000 microfarad capacitance. Therefore, more guidance than "porous materials increases the capacitance" is needed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 86 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 86, the claim is incomplete for omitting essential structural relationship to any other element in claim 43. The claim needs to connect the sensing electrode and second connection means to another element in claim 43 since the combination of claims 86 and 43 amounts to a mere listing of parts.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41, 43, 44, 45/(41, 43, 44), 74, 75, 78, 87, 91, and 94 are rejected under 35 U.S.C. 102(b) as being anticipated by Botvidsson et al (4611604). Botvidsson discloses in column 3, line 15, a lead diameter of 3 mm, in line 25, an electrode length of 0.5 mm and in column 4, line 21, the use of a capacitance of 10-100 mF per centimeter squared. Using 10 mF and the surface area of the electrode provides a capacitance of approximately 470 microFarads. Botvidsson shows in figure 1 the lead and describes the use of the lead with a pacemaker (e.g. col. 3, line 5) and therefore the lead inherently has a connection means for connection to a control means since the lead must have some sort of connector/connection to the pacemaker to control delivery of the pulses. In addition, Botvidsson's electrode, 2, and lead are capable of meeting the functional use recitations presented in the claims such as being a signal delivery electrode, for delivering a non-excitatory field, being used for the coronary sinus, etc., since an electrode is just a conductor used to establish electrical contact (i.e. to sense or stimulate) and Botvidsson's electrode is a conductor that is capable of doing both and since Botvidsson

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provides a 3 mm flexible lead. In addition, since the pulse used with electrode 3 is returned/grounded through electrode 2, electrode 2 is a signal delivery electrode. Also, it is noted that the claims are directed only to the lead and only contain positive limitations to the electrode and connector and not to any element to apply a pulse. For claim 44, it is noted that the control means has only been functionally recited in claim 43, and that the lead and electrode of Botviddson is capable of meeting the functional use recitations presented in the claim since the electrode, 2, can perform those functions.

Claims 41, 43, 44, 45/(41, 43, 44), 87, 91, and 94 are rejected under 35 U.S.C. 102(b) as being anticipated by Mund et al (4603704). Mund discloses an example of a hemispherical electrode head having a diameter of 2mm with a capacitance of 21.5mF/cm squared (e.g. col. 6) providing a capacitance of 1350 microfarads. In addition, Mund states that his electrode is for use with pacemakers to deliver pulses (e.g. col. 1, line 30, col. 4, line 2) and therefore the lead inherently has a connection means for connection to a control means since the lead must have some sort of connector/connection to the pacemaker to control delivery of the pulses. In addition, Mund's electrode is capable of meeting the functional use recitations presented in the claims such as being a signal delivery electrode and for delivering a non-excitatory field, since an electrode is just a conductor used to establish electrical contact (i.e. to sense or stimulate) and Mund's electrode is a conductor that is capable of doing both. Also, it is noted that the claims are directed only to the lead and only contain positive limitations to the electrode and connector and not to any element to apply a pulse. For claim 44, it is noted that the control means has only been functionally recited in claim 43, and that the lead and electrode of Mund is capable of

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meeting the functional use recitations presented in the claim since the electrode can perform those functions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19, 45/19, 76, 77, 80, 82, 84, 86, 88-90, 92, and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Botviddson or Mund.

Botviddson or Mund discloses the claimed invention except for: the different materials for the electrode, such as titanium coated with iridium oxide, platinum iridium coated with titanium nitride, platinum iridium coated with sintered platinum, or pyrolytic carbon; the lead diameter smaller than 1.5/1.2 mm; the electrode longer than a pacing electrode and shorter than a defibrillation electrode; the electrode being longer than 10 mm and shorter than 40 mm; the electrode having an impedance from 50-500 Ohms; and the sensing electrode and second

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connection means. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the heart leads as taught by Botviddson or Mund, the different materials for the electrode, such as titanium coated with iridium oxide, platinum iridium coated with titanium nitride, platinum iridium coated with sintered platinum, or pyrolitic carbon; the lead diameter smaller than 1.5/1.2 mm; the electrode longer than a pacing electrode and shorter than a defibrillation electrode; the electrode being longer than 10 mm and shorter than 40 mm; the electrode having an impedance from 50-500 Ohms; and the sensing electrode and second connection means since it was known in the art that heart leads use: different materials for the electrode, such as titanium coated with iridium oxide, platinum iridium coated with titanium nitride, platinum iridium coated with sintered platinum, or pyrolitic carbon since these materials are conventional materials that are biocompatible and have been tested/used in pacemaker leads to effectively pace and sense electrical signals; the lead diameter smaller than 1.5/1.2 mm to provide a small, unobtrusive lead that does not block any heart passages or veins; the electrode longer than a pacing electrode and shorter than a defibrillation electrode to provide the appropriate current density to the heart to effectively sense or apply stimulation to the heart; the electrode being longer than 10 mm and shorter than 40 mm, to provide the appropriate current density to the heart to effectively sense or apply stimulation to the heart; the electrode having an impedance from 50-500 Ohms to provide a low impedance electrode that does not waste battery energy; and the sensing electrode and second connection means to provide additional sensing and pacing electrodes to sense other chambers and areas of the heart or allow the other electrodes to operate in a bipolar mode.

Response to Arguments

Applicant's arguments filed 1/31/07 have been fully considered but they are not persuasive. It is noted that the arguments of counsel cannot take the place of evidence in the record (In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). MPEP 716.01(c)) and that the applicant's response/answers to the questions posed in the 112 first paragraph rejection may be correct, but those answers do not overcome the fact that the claims contain subject matter which was not described in the original specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 2/2/07 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

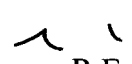
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945.

The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


George R Evanisko
Primary Examiner
Art Unit 3762

7/1/07

GRE
July 1, 2007